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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,930	10/11/2001	Michael Poirier	560.09-US1	4572

34284 7590 09/22/2006

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,930

Applicant(s)

POIRIER ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,9,10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 9, 10 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-6, 8 and 11 have been cancelled. New claims 15-20 have been added. Claims 7, 9, 10, 12-20 are currently pending.

Drawings

The drawing is objected to because the figure must not be numbered since there is only one figure (see Rule 1.84(u)(i)). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. **(The Office notes that similar correction must be made in the amended specification relating to the brief description of the drawing.)** Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 16 is objected to because of the following informalities: a period needs to be inserted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 9, 10, 12-14 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

At least two compartments in fluid communication with the fluid discharge port (see page 7, line, 27 – page 8, line 1) are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant states on page 7, line 27 – page 8, line 1 that “it should be appreciated that by employing at least 2 compartments (here:134 and 136) in fluid communication with the fluid discharge port 120, a continuous discharge of depleted biological fluid is achieved.” Because Applicant claims the step of emitting a continuous flow of processed whole blood (see claim 7, line 6), the limitations regarding providing at least two compartments in fluid communication

with the fluid discharge port is critical or essential to the practice of the invention according to the specification on pages 7-8. Claim 7 is missing essential elements to the extent that claim 7, lines 3-4, encompasses an embodiment wherein the plurality of compartments are fluidly coupled to the fluid receiving port and are not necessarily fluidly coupled to the fluid discharge port, which is critical or essential according to Applicant's specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Southgate et al., 5,863,502.

As to claim 15, Southgate et al. disclose a method of continuously separating whole blood, comprising:

providing a container having a flexible top sheet (i.e., flexible upper film, col. 11, lines 46-47 and col. 12, lines 42-43, and col. 10, line 59), a fluid receiving port (i.e., port near 143A in fig. 5a, and see col. 16, line 63), a fluid discharge port (i.e., port near 143B

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in fig. 5a, and see col. 16, lines 63-64), and a plurality of compartments (see col. 12, line 16 and 39-44, disclosing a plurality of reaction compartments between upper film 110 and lower film 120) fluidly coupled to at least one of the fluid receiving port and the fluid discharge port (see ports, i.e., openings, near 143A and 143B in fig. 5A, and col. 16, lines 63-64);

introducing whole blood into the fluid receiving port and emitting processed whole blood that is at least partially depleted of target antigen (col. 16, lines 62-64);

wherein the target antigen (col. 30, line 60-64, and col. 31, lines 18-36, disclosing an antibody attached to a solid support) is separated from the whole blood (col. 28, lines 61-62) within at least one of the plurality of compartments using a magnetic force (col. 26, lines 21-39) and an automatic mechanical force (see col. 19, lines 50-53, disclosing a device for pumping each reaction chamber 160; col. 23, lines 13-18, disclosing several pumping mechanisms that can be utilized with the invention) , wherein at least one of the magnetic force and automatic mechanical force is transmitted through the flexible top sheet (col. 26, lines 25, lines 65-66, disclosing magnets brought adjacent to the device; see also col. 23, lines 13-18, disclosing a roller or plungers pressing on the flexible film of the fluid chamber);

wherein a plurality of actuators in a device retaining the container compress at least some of the compartments in a predetermined manner to thereby move the whole blood and the processed whole blood through the plurality of compartments (see col. 19, lines 50-53, disclosing a device for pumping each reaction chamber 160; col. 23,

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lines 13-18, disclosing several pumping mechanisms that can be utilized with the invention.)

As to claim 16, a plurality of compartments and fluid conduits that fluidly couple one compartment to another compartment are formed by the top and bottom sheets (col. 12, lines 16 and lines 39-44).

As to claim 17, at least one of the compartments further includes a port that allows draining of the at least one of the compartments (i.e., one of the other compartments disclosed in col. 12, lines 16 and lines 39-44, which has a port for draining from the compartments, such as disclosed in col. 16, line 63).

As to claim 18, at least one of the compartments or at least one of the conduits that fluidly couple the compartments is configured such that an actuator can compress the conduit to partially or completely stop flow of the whole blood or processed whole blood through the conduit (see col. 16, lines 64-67).

As to claim 19, at least one of the compartments includes a fluid, specifically a buffer (col. 15, lines 18-19).

As to claim 20, the affinity marker is antibody (col. 30, line 60-64, and col. 31, lines 18-36, disclosing an antibody attached to a solid support).

Allowable Subject Matter

Claim 7 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 9, 10 and 12-14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach a method comprising providing a container with a plurality of compartments and introducing a continuous flow of whole blood into a port while at the same time emitting a continuous flow of processed whole blood that is at least partially depleted of a target antigen, using a magnetic force and an automatic mechanical force, and a plurality of magnetic beads in at least one of the compartments, wherein the entire container is flexible. The container in the Southgate reference has elements that do not make the entire container flexible (Fig. 5A for example).

Response to Arguments

Applicant's arguments filed July 5, 2006 have been fully considered. Applicant amended claim 7 (and thus its dependent claims) to conform to claim 11, which was indicated as having allowable subject matter in the previous Office action. However, upon further consideration, claim 7 (and thus its dependent claims) is missing essential or critical elements as indicated above. Also, Applicant's new claims 15-20 are rejected under Southgate et al. and thus are not allowable because they do not recite that the entire container is flexible.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Ann Lam 9/15/06